REMARKS

Pending Claims

Claims 2-4 and 6-20 are withdrawn as being drawn to nonelected inventions.

Claims 1 and 5 are under consideration.

Applicants reserve the right to prosecute non-elected subject matter in subsequent divisional applications.

Restriction Requirement

Applicants reiterate their traversal to the Restriction Requirement for at least the reasons already made of record, and remind the Examiner that, *upon allowance* of claim 1, it is believed that claims 2 (drawn to a method for producing a polypeptide of claim 1) and claims 6-9 (drawn to methods of using a polypeptide of claim 1) should be rejoined and considered, in accordance with the Commissioner's Notice in the Official Gazette of March 26, 1996, entitled "Guidance on Treatment of Product and Process Claims in Light of *In re Ochiai, In re Brouwer,* and 35 U.S.C. § 103(b)," which sets forth the rules, upon allowance of product claims, for rejoinder of process claims covering the same scope of products.

Rejection of Claims 1 and 5 under 35 U.S.C. § 102(b)

Applicants traverse the rejection of claims 1 and 5 for at least the following reasons.

The Examiner alleges that Applicants are barred by the autoantigen taught by Cohen et al. in U.S. Patent 5,312,628. This patent, however, does not disclose each and every limitation of Applicants' present claim to a polypeptide having SEQ ID NO:1 because it does not disclose the amino acid sequence of SEQ ID NO:1. In the absence of the amino acid sequence of the molecule described by Cohen et al., the Examiner is relying on inherency, saying that an amino acid sequence is an inherent property of a protein. However, the Examiner has provided *no concrete evidence* that Applicants' polypeptide having SEQ ID NO:1 and the autoantigen of Cohen et al. are the same molecule.

When relying on inherency for a rejection under 35 U.S.C. §102 an Examiner is required to provide evidence that a particular characteristic *necessarily* results from the disclosure or teachings of the prior art. "The mere fact that a certain thing *may* result from a given set of

circumstances is not sufficient" (emphasis added) (*In re Oelrich*, 212 USPQ 323,326 (CCPA 1981)). The court further defined the Examiner's burden in *Ex parte Levy* (17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)),

> "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art" (emphasis in original).

Applicants respectfully submit that the Examiner has not met this burden. Cohen et al. describe an autoantigen that has an approximate molecular weight of 40 to 45 kDa and reacts with autoantibodies of persons with diabetes. However, Cohen et al. do *not* disclose the sequence of said autoantigen. The Examiner estimates that Applicants' polypeptide, which is an autoantigen involved in diabetes, has a molecular weight of approximately 39,500 Da. The Examiner asserts that this estimation of molecular weight coupled with the polypeptide's role as an autoantigen is enough to conclude that it is molecule described by Cohen et al. The Examiner further asserts that Applicants' amino acid sequence of SEQ ID NO:1 is inherent in the protein described by Cohen et al.

While it is possible that Applicants' amino acid sequence *may* result from the autoantigen taught by Cohen et al., it does not *necessarily* result from it. There are many examples in the literature of autoantigens implicated in diabetes (e.g., insulin, proinsulin, GAD65, ICA69, ICA512, phogrin) (Hutton and Eisenbarth, PNAS 100:8626-8, 2003, attached as Exhibit A; Roep, Diabetes 45:1147-56, 1996). Moreover, there are further reports of autoantigens with the approximate molecular weight of the molecule described by Cohen et al. For example, Honeyman et al. describe a nuclear transcription protein, jun-B, having a molecular weight of approximately 38,000 Da, which reacted with the T cells of patients with recent-onset diabetes (Diabetes 42:626-30, 1993; abstract attached as Exhibit B). In another example, Leiberman et al. report yet another autoantigen that may have implications in diabetes, islet-specific glucose-6-phosphatase catalytic subunit-related protein (IGRP), having a molecular weight of approximately 38 kDa (PNAS 100:8384-8, 2003; attached as Exhibit C). Applicants submit that it is just as likely that the molecule described by Cohen et al. could be any of these or other autoantigens as the molecule claimed by Applicants.

In summary, the Examiner has not met his burden of showing that Applicants' amino acid sequence of SEQ ID NO:1 *necessarily* results from the protein disclosed by Cohen et al. Indeed, the numerous examples in the literature of autoantigens that are potentially involved in the onset of autoimmune diabetes suggest that a reliance on an approximate molecular weight and antigenicity is insufficient to accurately determine identity. Without the amino acid sequence of the autoantigen by Cohen et al., there is no basis to conclude that that molecule is the same as Applicants' molecule or one of the numerous other potential diabetes autoantigens. Applicants' therefore respectfully request that this rejection be withdrawn.

CONCLUSION

In light of the above amendments and remarks, Applicants submit that the present application is fully in condition for allowance, and request that the Examiner withdraw the outstanding rejection. Early notice to that effect is earnestly solicited.

If the Examiner contemplates other action, or if a telephone conference would expedite allowance of the claims, Applicants invite the Examiner to contact the undersigned at the number listed below.

Applicants believe that no fee is due with this communication. However, if the USPTO determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. **09-0108.**

Respectfully submitted,

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Attachments:

Exhibit A: Hutton, J.C. and Eisenbarth, G.S., "A pancreatic β-cell-specific homolog of glucose-6-phosphatase emerges as a major target of cell-mediated autoimmunity," PNAS 100:8626-8 (2003).

Exhibit B: Honeyman, M.C. et al.,"Transcription factor jun-B is target of autoreactive T-cells in IDDM," Diabetes 42:626-30 (1993), abstract.

Exhibit C: Lieberman, S.M. et al., "Identification of the β cell antigen targeted by a prevalent population of pathogenic $CD8^+$ T cells in autoimmune diabetes," PNAS 100:8384-8 (2003).